



Technical Service Bulletin

Blood Pressure Products

Welch Allyn, Inc.[®]
8500 SW Creekside Place
Beaverton, Oregon 97008-7107 USA

Bulletin Type: Information Only

Tel: 1-800-289-2501 Fax: 1-503-526-4910
www.WelchAllyn.com

Date: 2011-06-28

SAP DIR #: 20012555

Subject: TSB-ProBP 3400 Software Version 1.03.03

Distribution Scope: WA Internal
WA Technical Support, Product Service, & International Service Centers

Product(s) Referenced: ProBP 3400

SW Version: 1.03.03

Summary: Software version 1.03.03 has been released for the ProBP 3400 device. This software version was implemented in production of ProBP devices starting with serial number 100000922511.

Issue: Opportunities to enhance the ProBP 3400 functionality and interface were identified for this release, including implementation of a Chinese character set and capability to select the blood pressure algorithm in use.

Action: This software version implements the Chinese language option, which is now accessible via the **Language** menu and at initial power-on.

This software version also implements a new menu to allow selection between the licensed SureBP blood pressure algorithm and the standard step blood pressure algorithm. This menu is only available on devices with the SureBP feature activated, and can be accessed via the following menu path: **Settings > Advanced > NIBP algorithm.**

Reference to Standards:

- 21 CFR Part 820, ISO 13485, MPD SOP-0002

Service Strategy: The 1.03.03 software has been loaded on PartnerConnect for distribution via the Welch Allyn Service Tool. Use the service tool to verify the current host firmware version on the device.

Quality Documents: **All service centers using SAP to record service transactions:** For each monitor serviced, record the service activity in SAP.

All other service centers and Field Service: For each monitor serviced, complete and file a service report and attach to the service DHR.

Notes:

1. Contact the Welch Allyn Complaints Department to initiate or process a medical device complaint resulting from this or other issues.
2. Drawings, illustrations, and part numbers in this document are for reference purposes only and subject to change.

End of Bulletin

Revision History					
Version	Description	Change #	Init	Release Date	Appr
A	TSB-ProBP 3400 Software Version 1.03.03	D*	CB	D*	D*
D* - Refer to SAP DIR digital signature log for approval details.					